

Reference Image Database to Evaluate Response (RIDER).

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NCI Cancer Imaging Program

NIBIB: Detail

NIST: Guest Scientist

NIST Workshop

Sept 14-15th 2006

- ▶ **Define RIDER**
- ▶ **Explain the motivation and contents**
- ▶ **Introduce the project participants**
- ▶ **Explain the IT infrastructure**
- ▶ **Identify the needs (for standards and validation)**
- ▶ **Criteria for success.**



- ▶ **RIDER is a web accessible public resource of *validated* image data for different organ systems-modalities employed to:**
 - Reduce the physical sources of uncertainty for data collection and analysis methods across different imaging platforms.
 - Permit optimization of these methods and their standardized assessment by benchmarking performance against this resource.
 - Potentially accelerate FDA approval, CMS reimbursement and commercial dissemination of these methods as a first read.
 - Design and implement this resource within a two year time frame to allow improved methods to be used in planned clinical drug trials.
- ▶ **Design the resource with the intent of making it scalable as a trans-agency initiative:**
 - Employ accepted patient confidentiality, data interoperability, image annotation and markup standards using open source tools.
 - Develop an imaging workspace that includes an array of open source validation and statistical tools.



Research Plan and Organizational Structure

► Nature of the Data:

- **Data Sources:** Collections from on going NCI (ACRIN, CALGB, CTEP) and privately funded PhRMA trails.
- **Data Types:** Initially CT and FDG PET CT for lung cancer, and DCE MRI, MRS and Optical for other organ systems, including phantom-other calibration data.
- **Data Format:** Meet caBIG data interoperability and scalability requirements, including image annotation and mark up.
- **Data Base Size:** Sufficient to differentiate the performance of different analysis tools (of the order of 1000 serial cases).

► Organizational Oversight:

- **Inter agency (NCI, NIBIB, FDA, NIST):** Collaboration with academia, cancer centers and industry.
- **Consensus on Validation Methods:** For example: Data base content, mark up, and functionality requirements to train and test change analysis methods, calibration data analysis.
- **Support:** *RIDER is a Pilot Project.* The Intent is to seek a public private partnership with both the imaging industries and PhRMA.





Inter-Agency Initiative: U01-Steering Committee

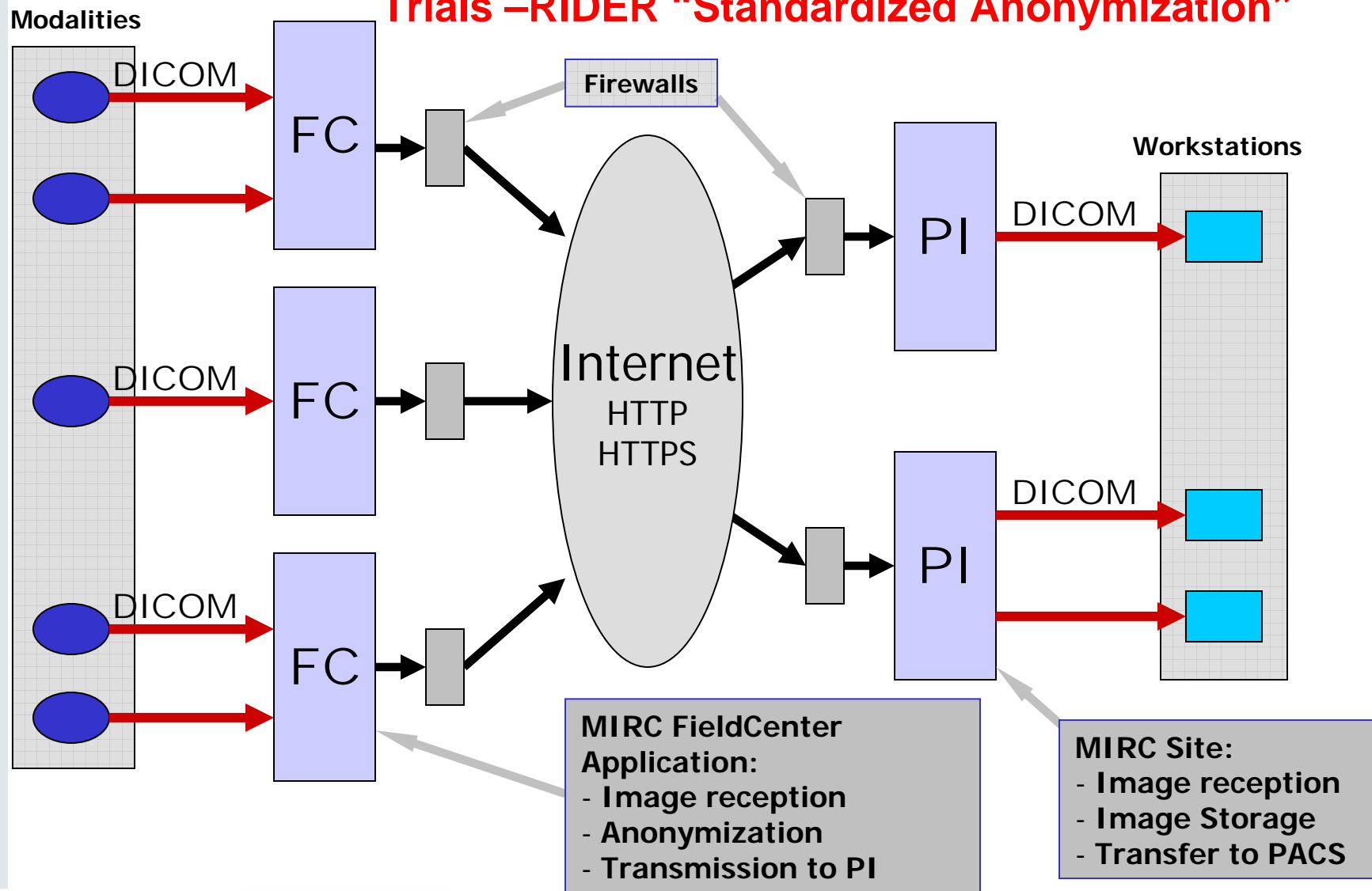


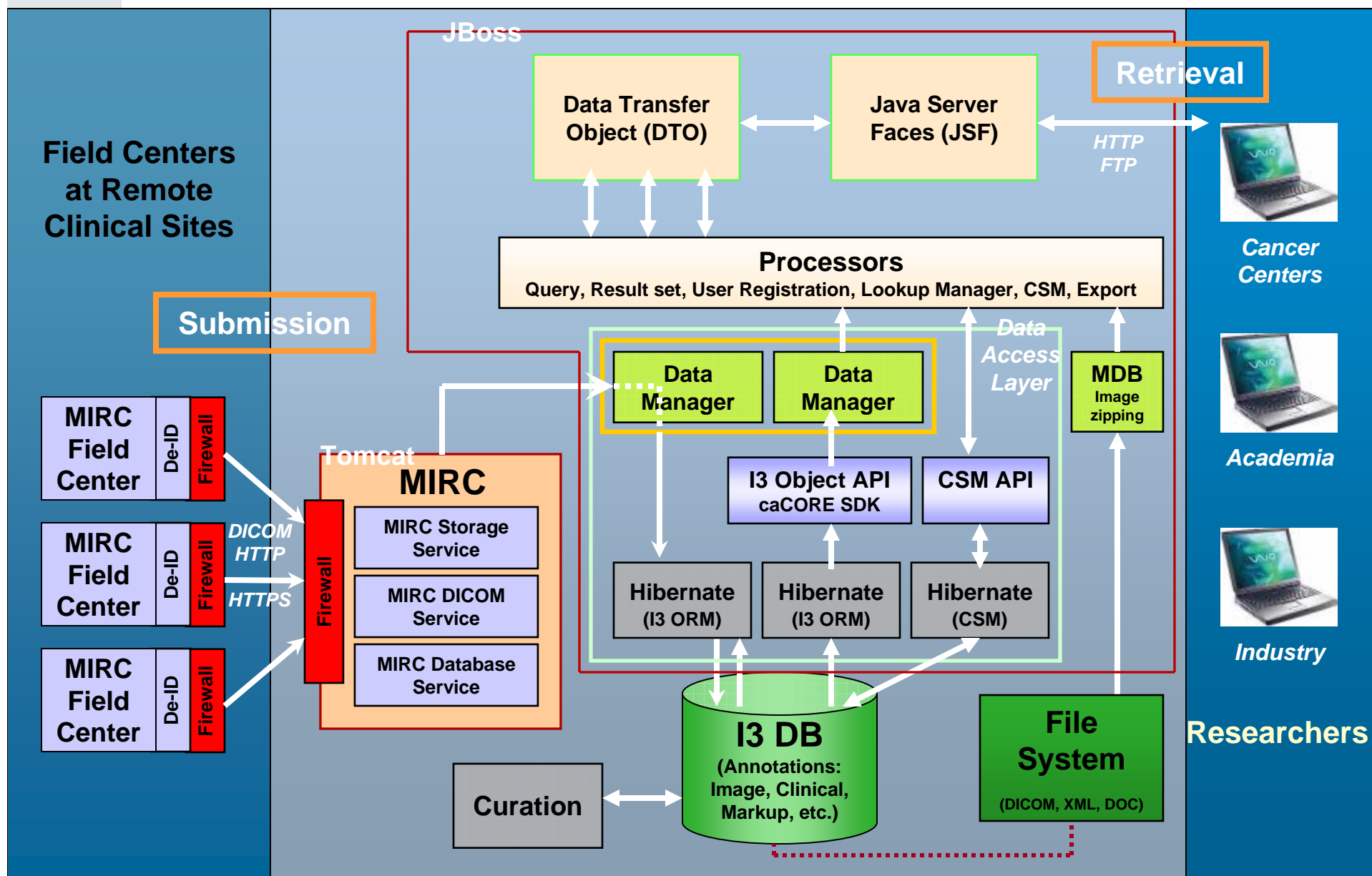
Laurence P Clarke PhD	NCI Extramural	Lead Science Officer (SO)
Barbara Croft PhD	NCI Extramural	Program Director
Carl Jaffe MD	NCI Extramural	SO: Clinical Protocols
Gary Kelloff MD	NCI Extramural	NCI-FDA: IOTF:OBQI
Dan Sullivan MD	NCI Extramural	NCI-FDA : IOTF:OBOI
Belinda Seto PhD	NIBIB Extramural	SO: NIBIB-FDA Intramural Program
Gary Becker MD, Eliot Siegel MD, John Perry	RSNA and NCI	MIRC: Image Collection, Meta Data Collection.
Kyle Myers, Nick Petrick, Bob Wagner	FDA CDRH Scientists	Database Design
Marios Gavrielides, Lisa Kinnard	NCI-NIBIB: Fellows	Statistical Methods
Charles Fenimore, others	NIST IT and other labs	NIST: Standards
Paul Kinahan PhD	NCI Visiting Scientist:	PET CT: Data Collection
University of Iowa, UCLA, Chicago, Cornell, Michigan, MDACC, MSKCC Other Sites Planned....	Leverage existing PPP LIDC-RIDER U01 Estab. 2001	CT Image mark up, Database Design and Demonstration of Functionality



NCI RSNA MIRC Clinical Trial Configuration

Resource for Data Collection from Pharma Trials –RIDER “Standardized Anonymization”







Imaging Archive: LIDC (IDRI PPP) and RIDER

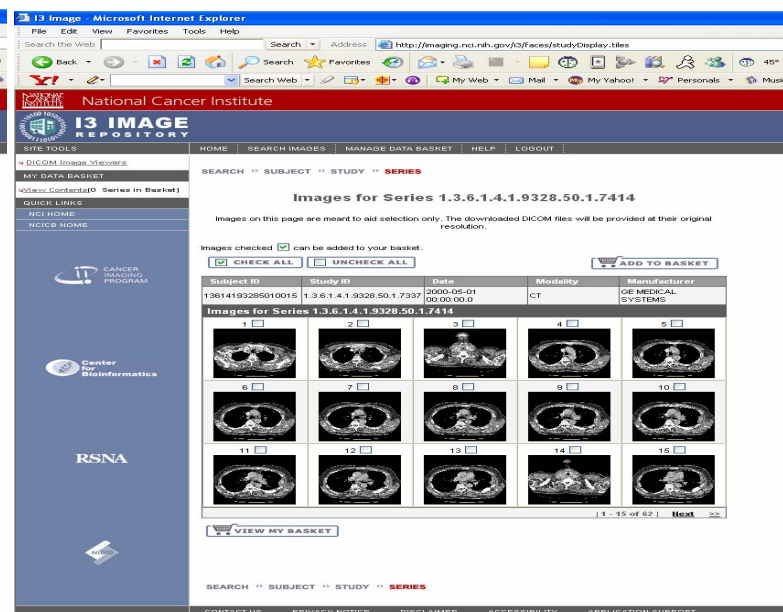
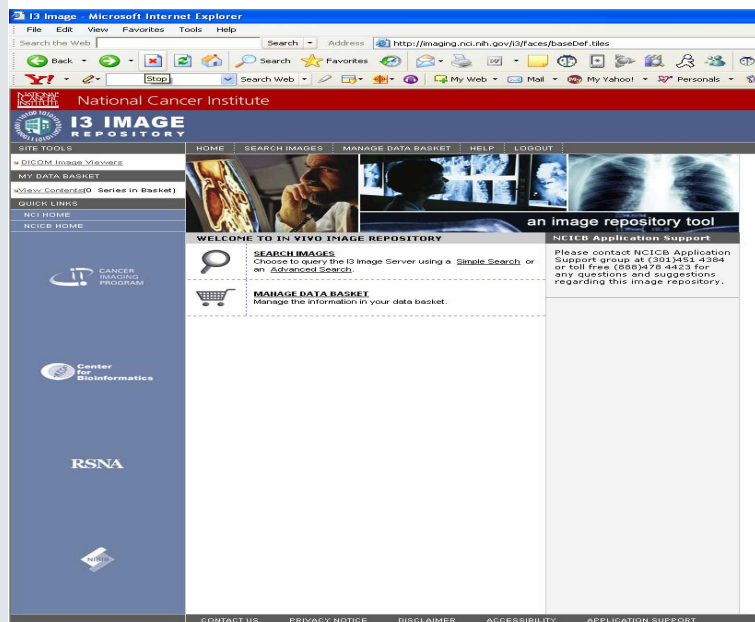
Advanced Web Query Based System: caBIG compatible

CT: Lung Screening: 500 cases, 220 annotated.

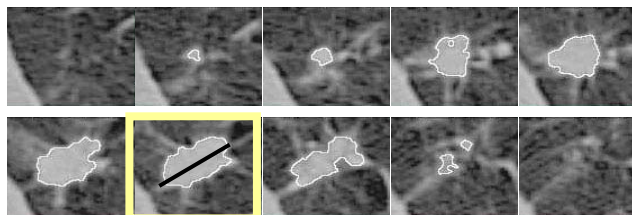
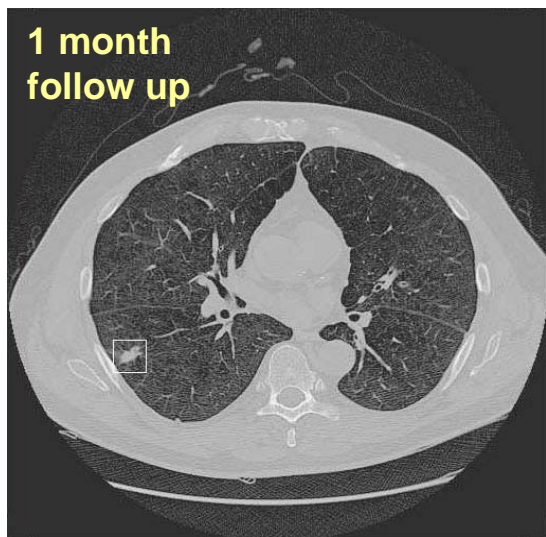
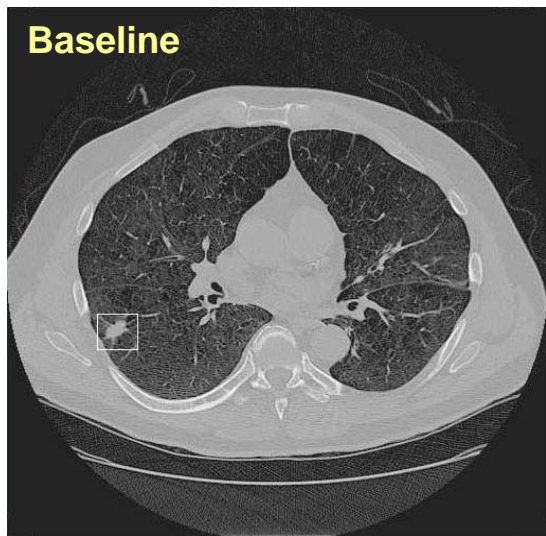
CT Lung: 100 serial CT cases, 30 annotated (RECIST), 200 by Dec 2006

PET CT Lung: Cases from Pharma, Academic Sites: Initiate by Oct 06

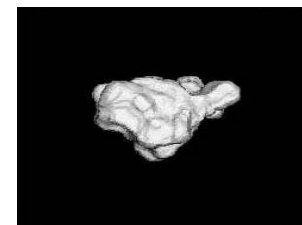
DCE MRI and other modalities and organ systems: In progress.



Aim: Relative comparison of change analysis methods

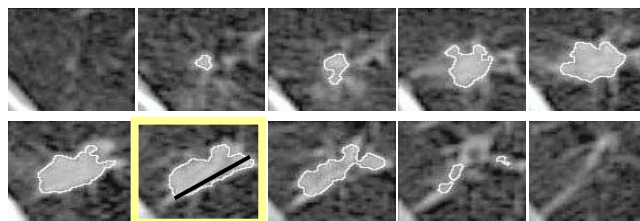
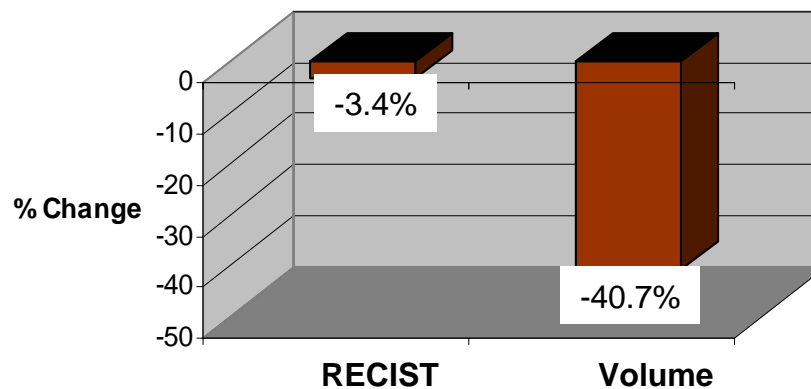


Diameter=17.7 mm



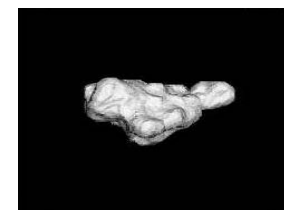
Volume=886 mm³

Percentage Change in the measurement



Diameter=17.1 mm

MSKCC DATA



Volume=525 mm³

Standards: Need for consensus for all levels of analysis.

Various Truthing possibilities:

Variance from software tools

Variance of phantom-based data

Expert-rated data

Imagery + mark up “truth”

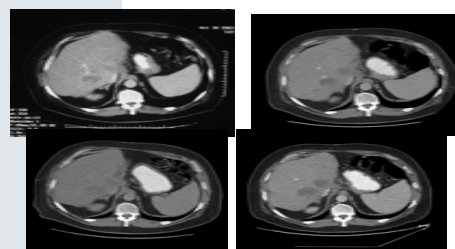


Image Registration



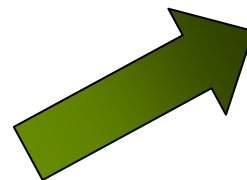
Developmental Set



Sequestered for Blind Evaluation

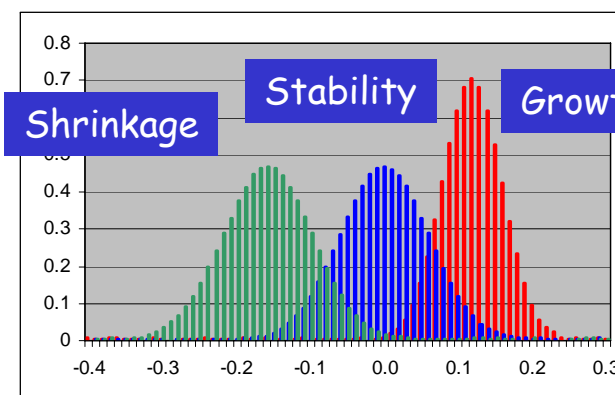


Change Analysis Tools



Standardized Statistical Performance Analysis

(Computer ROC)



Accommodate Different Features:
Volume, shape, pixel intensity/density changes, other.....

Standards: XML mark up



Leveraging Trans Agency Collaboration

- ▶ **NCI PAR: R01: Industry Academic Partnerships: April 07**
 - Support databases and open source validation tools
 - Open architecture for image data collection-analysis
 - Support travel-collaboration with FDA and NIST scientists
- ▶ **NCI-FDA MOU's: Research Collaboration.**
 - LIDC, and first PPP: IDRI 5-10-05
 - RIDER second PPP: 2006-07
- ▶ **NCI-NIBIB NIST MOU: Planned**
- ▶ **NIBIB FDA CDRH: Intramural Program**
 - NCI-NIBIB Funded Fellowship.
 - NIBIB Funded Fellowship.
 - Scope: Statistical methods for change analysis
- ▶ **Trans NIH Roadmap Initiative: Integrated IT Infrastructure?**





Interagency Biomarker Initiative.



- ▶ **Oncology Biomarker Qualification Initiative (OBQI):**
 - MOU Between the NCI, FDA, CMS: Clinical trials
 - NCI: Identify biomarkers that provide a means to measure therapy response
 - FDA: Qualification of biomarkers as clinical assessment tools
 - CMS: Informed reimbursement decisions for biomarkers
- ▶ **Inter Agency Biomarker Consortium (BC)**
 - Target Date for Announcement: Fall, 2006.
- ▶ ***RIDER: Proposal (Submitted Aug 2006 to BC)***
 - NCI resource as an initial goal.
 - Integrated interagency IT and software tools resource
 - Organizational model for trans-agency collaboration.
 - Interagency-Matching funds (50%)



- ▶ **Need to engage the imaging and software companies as active stakeholders in the planned *Biomarker Consortium* to create this technology resource.**
- ▶ **Need for the imaging scientific societies to collectively become active stakeholders in the creation of imaging reference standards and related resources.**
- ▶ **Need for imaging industry to explore more standardized or cross validation approaches for data collection and analysis methods, and ideally incorporate these performance requirements into current and emerging platforms.**

- ▶ NCI NCIA: <http://ncia.nci.nih.gov/ncia/collections>
- ▶ NCI RIDER Resource and RIDER White Paper
<http://ncia.nci.nih.gov/ncia/collections>
- ▶ NCI IRAT: <http://www.aaci-cancer.org/irats/infosupport.asp>
- ▶ NCI OBQI:
<http://www.cancer.gov/newscenter/pressreleases/OBQI>
- ▶ NIST Workshop:
<http://usms.nist.gov/workshops/bioimaging.htm>
- ▶ NCI FNIH Image Database Imaging Resource: IDRI PPP:
http://www.fnih.org/partners/research_environment/IDRI.shtml
- ▶ NIH Roadmap: <http://nihroadmap.nih.gov/>